

Claims 1-5, 7-17, 30, and 31 are pending in the subject application.

In paragraph 6 of the Action, claim 31 stands rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons made of record in Paper No. 8, mailed 11-10-97.

Applicants are confused. In paragraph 4, on page 2 of the Office Action, Examiner withdraws the rejection of claim 31 under 35 U.S.C. 112, first paragraph in view of Applicants' claim amendment. In addition, no rejection of claim 31 is found in Paper No. 8. The reference to Paper No. 8, mailed 11-10-97 is inapplicable since claim 31 was added by amendment in the Response dated February 22, 1999. Applicants request clarification and correction.

Claims 1-3, 5-17, and 30 stand rejected under 35 U.S.C. §103(a) as allegedly obvious over WO95/18231 (Titball et al. -'31) and further in view of: WO 95/24475 (Titball et al. -'75); or Leary et al. *Infection and Immunity* **63**: 2854-2858, 1995). This rejection is traversed in view of the following.

Titball et al. -'75, WO95/24475 was publicly available on 14 September 1995, less than one year before the filing date of the claimed invention. A declaration under Rule 1.131 is herewith submitted showing facts that establish that the

claimed invention was conceived and reduced to practice in the United States prior to the publication date of Titball et al. - '75. In view of the 1.131 declaration, Applicants respectfully request removal of the reference.

The remaining cited references do not render the invention obvious. Titball '31 do not describe a fusion protein in the sense that the final isolated protein product is composed of two different, complete proteins. The constructs described in Titball '31 include the construct pFSIG3a, which, as Examiner correctly points out, contains the F1 sequence "fused" with the *E. coli* LTB signal sequence. The signal sequence gets clipped off during translation of the protein on the ribosome such that the isolated product is F1 only. The other construct described in Titball '31, pFGAL2a, contains the F1 sequence cloned downstream from a lacZ promoter, a sequence not translated and therefore not found in the final protein product. Therefore, Titball et al. - '31 produces recombinant F1 where the final isolated protein is only F1 and not a fusion protein.

Leary et al., 1995, describes a V antigen as a fusion with glutathione S-transferase but does not describe or suggest a F1 fusion, or a F1-V fusion protein.

Therefore, neither reference describes or suggests a F1-V fusion protein. No prior knowledge or teaching existed for fusing two complete antigens, F1 and V, such that protective epitopes of both antigens would be retained. Since the references cited do not provide guidance for producing a F1-V

fusion protein, undue experimentation would be necessary without reasonable expectation of success. Hence, the cited art may render the invention, at best, "obvious to try". However, this is not the standard of 35 U.S.C. §103(a). Therefore, neither Titball '31 nor Leary et al., alone or in combination, render the invention obvious. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 6 stands objected to under 37 CFR 1.75(c) and rejected under 35 U.S.C. 102(b) as allegedly anticipated by GenEMBL Accession Number M26405. The cancellation of this claim renders this rejection moot. Withdrawal of the rejection is respectfully requested.

All objections and rejections have been addressed. This application is believed to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class mail in an envelope addressed to the Commissioner of Patents, Washington, D.C. 20231 on July 31, 2002.

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